REMARKS

Claims 1-7, 9-21, 25, and 27-33 are pending in the application.

Claims 8, 22-24, and 26 are cancelled without prejudice.

Claims 1, 3, 7 and 13 are amended herein to correct claim dependency and to provide or correct antecedent basis.

New claims 29-33 are added. Claim 29 depends from Claim 1 and is supported by original claim 11. Claim 30 is dependent to Claim 9, and identifies additional components in the topical composition. Claims 31 and 32 depend through to Claim 30, and are supported by original Claim 10. Claim 33 is dependent to Claim 30 and is supported by original Claim 10.

No new matter has been added by way of the claim amendments.

Elections and Restrictions

The Examiner requires restriction of the claims to four distinct inventions, as follows:

I. Claims 1-5, stated as drawn to a composition comprising R-equol for making commercial products, classified in class 514 subclass 456.

II. Claims 6-8, stated as drawn to a food composition comprising R-equol, classified in class 424 subclass 439.

III. Claims 9-11, stated as drawn to a composition for topical use comprising R-equol, classified in class 514 subclass 887 and 947, and class 424 subclass 401 and 78.03.

IV. Claims 12-28, stated as drawn to a method of delivering R-equol to a mammal to prevent or treat a disease or associated condition, classified in class 514 subclass 456.

Because the Office requires election in any response, Applicants provisionally elect Group I and Claims 1-5 that read on Group I, with traverse. Applicants will withdraw any further non-elected claims and make any further necessary claim amendments after the Restriction Requirement has been made final. Applicants now add new Claims 29-33. Consequently, Group I now includes after amendments, independent Claim 1 and dependent Claims 2-5 and 29. The remaining Groups include after amendment: Group II, Claims 6-8; Group III, Claims 9-12 and 30-33; and Group IV, Claims 12-21, 25, and 27-28.

Traversal of Restriction Requirement

A requirement for restriction is properly made only when (1) there are two or more patentably independent and distinct inventions, and (2) the inventions cannot be simultaneously examined without serious burden on the examiner. Applicants respectfully submit that the Restriction requirement is not proper because it would not constitute a serious burden to search and consider each of the inventions. Each of the Groups is linked by the concept that a composition comprising or consisting essentially of R-equol can be administered to prevent or treat a disease. It is respectfully submitted that a complete patentability search for any one of the claimed inventions would seem to properly involve a search of references primarily pertaining to the other claimed inventions because the Examiner might want to consider whether a reasonable suggestion of one of the claimed inventions could also reasonably be deemed to extend to the other claimed inventions. Accordingly, Applicants respectfully request that each of the identified inventions (defined by Groups I to IV) be examined together.

The allegations raised in the Office Action are addressed below:

a. Inventions of Group I and Group II

The Office Action alleges that Groups I and II are distinct as a combination and sub-combination, and states as reasoning that the combination as claimed does not require the particular of the subcombination as claimed because the composition does not require food component of the subcombination. The subcombination has separate utility such as a food or dietary supplement.

Applicants traverse the argument of the Office. The Examiner argues that composition comprising R-equol for use in making commercial products is the "combination", while the food composition comprising R-equol is the subcombination. This appears to be incorrect. A combination is an organization of which a subcombination or element is a part. The subcombination (as one might apply that term to a composition) is the invention of Group I, and the combination is the invention of Group II. Two-way distinctiveness is required, wherein: (1) the combination as claimed does not require the particular of the subcombination as claimed for patentability; and (2) that the subcombination has utility by itself or in other combinations.

As the restriction is improperly presented, Applicants request that it be reconsidered and withdrawn.

b. Inventions of Group I (and II) and Group III

By the same rationale and for the same reason (that this restriction is improperly presented), Applicants request that it also be reconsidered and withdrawn.

c. Inventions of Group I (and II and III) and Group IV

The Examiner alleges that Inventions I-III and IV are related as product and process (or method) of use, and the product (Group I, II or III) can be used in a materially different process of using that product. In the instant case, the Examiner states that the materially different process is to enhance skin penetration.

Applicants traverse the argument.

The Examiner's allegation that the products can be used to enhance skin penetration can not be demonstrated and lacks technical support. The Applicant's description does not mention this benefit or use. Although a topical composition of the invention can include an optional skin penetration agent (for enhancing the penetration of R-equol into the skin), it does not necessarily render that function to the composition. Since the Examiner's restriction requirement has inaccurate support, the Applicants request that it also be reconsidered and withdrawn.

Rejection over Alvira

The Examiner rejects claims 1-3 under 35 USC 102(b) as anticipated by Alvira et al (Molecular modeling study for chiral separation of equol enantiomers by beta-cyclodextrin, vol. 240, issues 1-5, 1999, pp. 101-108). The Examiner alleges that Alvira teaches the separation of R-equol from S-equol, which meets the limitation of a composition comprising R-equol.

Applicants traverse.

Alvira discloses merely a theoretical use of cyclodextrin as a separation media for the enantiomers of equol, based on a statistical analysis of the minimum energies of the R-equol and S-equol structures. The authors note contradictions between the molecular modeling and experimental findings, which (it appears) are not disclosed in the reference, and indicate that additional study of the solvation effect is required (at page 7, the end of Section 3.4, Chiral Recognition).

Applicants can find no description in Alvira of an actual separation of a racemic or other mixture of equol into the R-equol and S-equol enantiomers, and no description of any process or method by which a person of ordinary skill in the art could effect such a separation, certainly not without significant additional development and/or trial and error, neither of which is disclosed or suggested by the authors. By way of example, and not limiting the traverse in any way, we note that no solvent is discussed or suggested.

Therefore, Applicants contend that the Examiner has not presented a prima facie case of enablement in the prior art. To be prior art under 35 USC 102(b), the reference must put the anticipating subject matter at issue into the possession of the public through an enabling disclosure. (Chester v. Miller, 906 F.2d 1574, 15 USPQ2d 1333 (Fed. Cir. 1990).

Further, Applicants note that the authors at the time of the author's publication did not know which of the equol enantiomers occurred in nature.

The newly presented claim 29 also depends from claim 1, and incorporates additional limitations that are neither disclosed nor suggested in Alvira. Likewise, none of the non-elected inventions of Groups II, III, and IV are either disclosed or suggested by Alvira.

Rejection over Alvira in view of Miller

The Examiner also rejects claims 4 and 5 under 35 USC 103(a) as obvious over Alvira. The Examiner alleges that Alvira does not disclose the presence of R-equol at 90 or 96% enantiomeric purity, but presumes that an artisan, provided with the technique of Alvira, would have been able to optimize the purity of R-equol through routine experimentation even to the level of 90 or 96% purity.

Applicant traverse.

As far as the Applicants can determine, there is no specific disclosure in Alvira of a technique, using cyclodextrin or otherwise, that would provide any separation of R-equol and S-equol from a mixture. As argued above, Alvira lacks enablement of the anticipating subject matter.

Moreover, the theoretical teaching in Alvira is directed to separating of equol enantiomers, not to forming a non-racemic mixture of the claimed enantiomeric purities.

Conclusion

Applicants contend that the prior art of record does not disclose or suggest the present claims, and request reconsideration and withdrawal of the rejections, withdrawal of the restriction requirements, and an allowance of all claims.

Respectfully submitted,

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